SEP 12 2002

K013644

Philips 510(k) Notice

AcQPlan 5.0

SUMMARY

The following information is being supplied in accordance with 21CFR 807.92(a) and in the order specified in that section.

1. Submitter

Philips Medical Systems, Inc.
595 Miner Road
Cleveland, OH 44143
(440) 483-3000

Contact

Robert L. Turocy
Philips Medical Systems
595 Miner Road
Cleveland, OH 44143
Telephone: 440 483 3528
FAX: 440 483 1116

Summary Date: November 1, 2001

2. Device Name and Classification

Device Name: AcQPlan 5.0
Classification Name: Radiation Therapy Planning System
Common Name: Radiation Therapy Planning System

The FDA has classified the AcQPlan 5.0 as Class II in 21 CFR 892.5840 (Product Code 90KPQ).

3. Comparison to Predicate Device

In the opinion of Philips, the AcQPlan 5.0 is Radiation Therapy Planning System is of comparable type and substantially equivalent to the legally marketed device, AcQPlan currently in commercial distribution under 510(k) Document control Number K974770.

4. Device Description

The AcQPlan 5.0 provides three-dimensional, external beam radiotherapy treatment planning (RTP) based on Philips Computed Tomography and Magnetic Resonance volume datasets. AcQPlan 5.0 is a fully integrated software package option to AcQSim virtual simulation software for dose calculation and evaluation. When used with the geometric-planning functionality of Philips AcQSim virtual simulation package, AcQPlan 5.0 users can simulate and plan a comprehensive course of radiotherapy in a single episode of patient care on a single workstation

5. Intended Use of the Device

The AcQPlan 5.0 is an integrated 3-D RTP and simulation system embedded in a volumetric image processing computer environment. AcQPlan 5.0 is intended to be used to plan radiation therapy treatments on linear accelerators and other similar teletherapy devices with x-ray beams of energies from 4 to 50 MV, cobalt-60, and electron beams with energies from 4 to 50 MeV of the entire human anatomy. It allows the treatment planner to employ such techniques as asymmetrically collimated fields, irregular fields, multi-leaf collimators, non-coplanar fields, bolus, and fixed wedges. It allows the treatment planner to take heterogeneities into account (CT only) for photon beams using two versions of the Batho method or the Equivalent TAR (ETAR) method, and it uses a generalized Gaussian pencil beam model for electron beams. Using AcQPlan 5.0, the treatment planner can simultaneously visualize target and normal tissues and the computed 3-D dose distributions in great detail, on a real-time basis. The treatment planner develops treatment plans in a coordinate system accurately fixed to set-up marks on the patient made possible by volumetric 3-D image processing. Tools for managing competing and complementary plans are provided. Tools, based on DVH plots, are provided for comparing competing plans. High quality DRS and DCS (digitally reconstructed or composited simulation) images, with BEV and beam graphics superimposed, are generated to replace conventional simulator films. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

Warning: In the United States, Federal law restricts this device to sale, distribution and use by or on the order of a physician.

6. Safety and Effectiveness Considerations

The safety of the AcQPLan 5.0 is assured by Philip's adherence to FDA GMPs designed to conform with International Standards. Potential hazards are identified in the Hazard Analysis (Attachment "F") and these hazards are controlled in the following manner:

Electrical and Mechanical safety is assured by adherence to IEC 60601-1 and UL 187
Radiation safety is assured by conformance to 21 CFR Subchapter "J" Performance Standards.

Radiation safety is assured by conformance to 21 CFR Subchapter "J" Performance Standards.

Software safety is assured by the Philip's LCM Procedures that conform to accepted practiccs. Quality assurance procedures and test results demonstrate that the AcQPlan 5.0 specifications and functional requirements functional are met. See Attachment "H" Software Lifecycle Management Process.

Effectiveness is established by Philips's evaluation throughout all phases of the AcQPlan 5.0 development. The product will perform in accordance with the development specifications.

7. Substantial Equivalence Statement

Based on the above considerations, it is the opinion of Philip's that the AcQPlan 5.0 Radiation Therapy Planning System is substantially equivalent to the predicate device the AcQPlan granted marketing permission in K974770. The AcQPlan 5.0 represents the current state-of- the-art technology, therefore, is equivalent to legally marketed devices.

The AcQPlan 5.0 is substantially equivalent to legally marketed devices referenced above. The AcQPlan 5.0 is under control of health care professionals who are trained and responsible for radiation therapy planning. Labeling (Product Specification and Operator's Manual) will be provided to the user of the equipment.

Philips has reviewed all known information and performed an investigation as to the causes of safety and effectiveness concerning the AcQPlan 5.0. In addition, all information contained in this 510(k) Notice is accurate and complete.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 12 2002

Mr. Robert L. Turocy
Regulatory Affairs Manager
Philips Medical Systems
595 Miner Road
CLEVELAND OH 44143

Re: K013644
Trade/Device Name: AcQPlan 5.0
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: 90 MUJ
Dated: June 21, 2002
Received: June 24, 2002

Dear Mr. Turocy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(K) Number (if known): **K0** 13644

Device Name: **AcQPlan 5.0**

Indications for Use:

The AcQPlan 5.0 is an integrated 3-D RTP and simulation system embedded in a volumetric image processing computer environment. AcQPlan 5.0 is intended to be used to plan radiation therapy treatments on linear accelerators and other similar teletherapy devices with x-ray beams of energies from 4 to 50 MV, cobalt-60, and electron beams with energies from 4 to 50 MeV of the entire human anatomy. It allows the treatment planner to employ such techniques as asymmetrically collimated fields, irregular fields, multi-leaf collimators, non-coplanar fields, bolus, and fixed wedges. It allows the treatment planner to take heterogeneities into account (CT only) for photon beams using two versions of the Batho method or the Equivalent TAR (ETAR) method, and it uses a generalized Gaussian pencil beam model for electron beams. Using AcQPlan 5.0, the treatment planner can simultaneously visualize target and normal tissues and the computed 3-D dose distributions in great detail, on a real-time basis. The treatment planner develops treatment plans in a coordinate system accurately fixed to set-up marks on the patient made possible by volumetric 3-D image processing. Tools for managing competing and complementary plans are provided. Tools, based on DVH plots, are provided for comparing competing plans. High quality DRS and DCS (digitally reconstructed or composited simulation) images, with BEV and beam graphics superimposed, are generated to replace conventional simulator films. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Prescription Use ✓ OR Over-The Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013644